


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Marc Peters-Golden *et. al*
Serial No.: 09/291,656
Filed: 03/03/99
Entitled: **Administration Of Products Of The 5-Lipoxygenase Metabolic Pathway To Enhance Antimicrobial Defense**
Group No.: 1653
Examiner: Carlson, K.

APPEAL BRIEF (SUBSTITUTE)
APPEAL NO.:

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Date: <u>Jan 17, 2006</u>	By: 
Christopher J. Collins	

Sir/Madam:

This Substitute Brief is in response to the Board Of Patent Appeals and Interferences "Order Returning Undocketed Appeal To Examiner" for an alleged lack of compliance to 37 CFR § 41.37(c) mailed December 20, 2005 and is in furtherance of the Notice of Appeal mailed on August 23, 2004. The Board's Order indicates that the pending brief is missing: i) "Summary of claimed subject matter" as set forth in 37 CFR § 41.37(c)(1(v)); ii) "Grounds of rejection to be reviewed on appeal" as set forth in 37 CFR § 41.37(c)(1(vi)); iii) "Evidence appendix", as set forth in 37 CFR § 41.37(c)(1(ix)); and iv) "Related proceedings appendix", as set forth in 37 CFR § 41.37(c)(1(x)).

The fees required under § 1.17(c) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This Brief contains these items under the following headings and in the order set forth below [37 CFR § 1.192(c)]:

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I. REAL PARTY IN INTEREST

The real party in interest is the Regents of the University Of Michigan, 3003 South State Street, Ann Arbor, MI 48109-1280.

II. RELATED APPEALS AND INTERFERENCES

There are no related applications pending appeal.

III. STATUS OF CLAIMS

1-21. (Canceled)

22. (Appealed) A solution for the treatment of a microbial infection, said solution comprising a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is an aerosol.

23. (Appealed) The solution of Claim 22, wherein said leukotriene is leukotriene B₄.

24. (Appealed) The solution of Claim 22, wherein said leukotriene is a cysteinyl leukotriene.

25. (Appealed) The solution of Claim 24, wherein said cysteinyl leukotriene is selected from the group consisting of leukotriene C₄, leukotriene D₄, and leukotriene E₄.

26. (Canceled)

27. (Appealed) The solution of Claim 22, wherein said microbial infection comprises *Klebsiella pneumoniae* infection.

28. (Appealed) A solution for the treatment of a microbial infection, said solution comprising a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is in an intratracheal instillation device, said instillation device is selected from the group consisting of an endotracheal tube and a bronchoscope.
29. (Appealed) The solution of Claim 28, wherein said leukotriene is leukotriene B₄.
30. (Appealed) The solution of Claim 28, wherein said leukotriene is a cysteinyl leukotriene.
31. (Appealed) The solution of Claim 28, wherein said cysteinyl leukotriene is selected from the group consisting of leukotriene C₄, leukotriene D₄, and leukotriene E₄.
32. (Appealed) The solution of Claim 28, wherein said microbial infection comprises *Klebsiella pneumoniae* infection.
33. (Appealed) A composition for the treatment of a microbial infection comprising, a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is contained within a nebulizer.
34. (Appealed) The composition of Claim 33, wherein said leukotriene is leukotriene B₄.
35. (Appealed) The composition of Claim 33, wherein said leukotriene is cysteinyl leukotriene.
36. (Appealed) The composition of Claim 33, wherein said cysteinyl leukotriene is selected from the group consisting of leukotriene C₄, leukotriene D₄ and leukotriene E₄.

37. (Appealed) The composition of Claim 33, wherein said microbial infection comprises *Klebsiella pneumoniae* infection.

The appealed Claims 22-25 and 27-37, as they now stand, are set forth in the Claims Appendix (Section VIII).

IV. STATUS OF AMENDMENTS

All amendments in the case have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The first independent claim (Claim 22) recites an aerosol (pg 53 ln 2-3) for the treatment of a microbial infection (pg 13 ln 17 - pg 15 ln 25) comprising a sterile liquid vehicle (pg 8 ln 28), an antibiotic (pg 14 ln 6; pg 18 ln 29) and a leukotriene (pg 10 ln 18 - pg 13 ln 15). This sterile aerosol is intended as a therapeutic preparation (pg 22 ln 7-11) and may be made with physiological tolerable liquids (pg 21 ln 17) and auxiliary substances (pg 22 ln 3)

The second independent claim (Claim 28) recites a sterile solution for the treatment of a microbial infection, the solution comprising a sterile liquid vehicle, an antibiotic and a leukotriene, wherein the solution is in an intratracheal instillation device (pg 40 ln 23 - pg 41 ln 24; pg 43 ln 13-14). Intratracheal leukotriene instillation was shown in Example 6 (pg 40 ln 22 - pg 41 - ln 24) and Example 10 (pg 50 ln 10) to be an effective antimicrobial therapy.

The third independent claim (Claim 33) recites a composition for the treatment of a microbial infection comprising, a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in the sterile liquid vehicle, wherein the solution is contained within a nebulizer (pg 29 ln 3 - 4); pg 53 ln 5-6).

VI. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

Claims 22-25 and 27-37 stand rejected under 35 U.S.C. 103(a) by United States Patent No. 5,789,441 To Gosselin et al. (hereinafter the '441 patent) as allegedly obvious..

VII. ARGUMENT

A. Rejection Under 35 U.S.C. 103(a) Over U.S. Pat No. 5,789,441

The Applicants provide below three separate issues related to the Examiner's present rejection. First, the Applicants believe that U.S. Pat. No. 5789,441 To Gosselin et al. (the '441 patent) is not properly cited prior art. Second, the Applicants believe that the Examiner has misinterpreted case law in determining that "an aerosol" has no patentable weight. Third, the Examiner has not presented a *prima facie* case of obviousness because not all the claim limitations are taught by the '411 patent.

1. Claims 22-25 & 27-37: The '441 Patent Is Not Prior Art

The '441 patent, as cited by the Examiner, was filed on February 11, 1997 as a continuation-in-part of the now abandoned United States Patent Application No. 08/602,059 To Gosselin *et al.* filed 02/15/96 (the '059 application)¹. The Applicants' pending divisional application has priority to United States Patent Application No. 08/757,136, filed on December 3, 1996. Clearly, the '441 patent was filed after the Applicants' '136 application. As such, the Examiner must find complete support for the present rejection in the '059 parent application.

The Examiner has not (apparently) reviewed the '059 application for support regarding the present rejection. The '059 application does not teach any aerosol or sterile solution compositions. Consequently, the '441 patent's "aerosol" (Col. 11, line 31) and "sterile solution" (Col. 12 line 15) teachings do not enjoy the '059 application's priority date. Without support in the '059 application for the Applicants' claimed elements of "aerosols" and "sterile solution" the '441 patent, therefore, is not prior art regarding the Examiner's present rejection.

¹ Applicants provided a copy of the '059 application to the Examiner in the *Second Final Office Action* response.

2. Claim 22: An Aerosol Has Patentable Weight

The Examiner invokes legal case citations of *Union Oil*, *In re Rosicky*, *In re Riden et al.* and *In re Lerner* to support the proposition that "While the claims recite that the solution [is] aerosolized this phrase[] is given no patentable weight". *Third Final Office Action*, pg. 3.² The Applicants disagree. The Applicants' claimed embodiment is directed to a composition of matter comprising "an aerosol" and contains no functional language. Because "an aerosol" is not functional language the Examiner MUST give this claim element full patentable weight.

The Examiner cites *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 54 USPQ.2D 227 (2000). Applicants submit the issues in *Union Oil* involve very different claim language. The claims at issue in *Union Oil* describe a composition that is "suitable for" a particular use (*i.e.*, conventional gasoline to be used in a standard automobile engine). The CCPA upheld the lower court interpretation that the term "suitable for" encompassed any standard automotive fuel and was not directed to specialty fuels (*i.e.*, aviation or racing fuels).

The term "suitable for," however, does not appear in the present claims. Indeed, there is no attempt to create patentable limitations through "intended use" language such as "suitable for". Applicants' claims specify elements - not how the elements are used. For example, Claim 22 requires that the solution is in the form of "an aerosol." This is not "suitable for" language - the term "aerosol" properly limits the form of the solution.

Second, the Examiner cites *In re Rosicky*, 47 CCPA 859, 125 USPQ 341 (1960). The Examiner is apparently relying on the *Rosicky* Court's rendering of a "pharmaceutical carrier" as obvious. This decision, however, was made in the context of the **absence** of any advantages established on-the-record:

Appellant has not established by any sort of clinical data that such a quantity would be a safe or useful dosage for the treatment of any particular malady, or useful for the alleviation of specific symptoms.

² The Applicants note the Examiner no longer includes "intratracheal instillation devices" as lacking patentable weight in reference to this case law. In the Examiner's Answer, the Applicants request a clarification stating that a rejection to these novel features have been withdrawn.

In re Rosicky at 865. By contrast, several advantages of the proposed compositions are taught within the Applicants' specification and appear in boldface type below:

A preferred mode of administration comprises administration to the lung. Patients who are sick enough to require **mechanical ventilation** can receive treatment with pharmacologic agents administered via the endotracheal tube which is connected to the ventilator. Alternatively, **intrapulmonary delivery** of pharmacologic agents to patients not requiring mechanical ventilation can be accomplished via aerosolization. Alternatively, the agent may be administered to the lung through a bronchoscope. Of course, the therapeutic agents may be investigated for their efficacy via other routes of administration, including parenteral administration. However, when the site of infection is the lung, **targeting drug delivery thereto is likely to minimize side effects and systemic consequences.**

Applicants' Specification, pg 22, ln 12 - 21 [emphasis added];
and,

To ensure **dosing limited** to the respiratory tract and to be able to **precisely quantitate** the dose administered ... *Applicants' Specification*, pg 53, ln 3 - 5. [emphasis added]

Thus, contrary to the facts of *In re Rosicky*, Applicants' specification provides the requisite evidence showing particular advantages of an aerosol. As such, the holding of *In re Rosicky* has no bearing on Claim 22.

The Examiner also cites *In re Lerner*, 169 USPQ 51 (1971). Applicants submit that *Lerner* is similar to *Rosicky* and is likewise inapplicable to the present claims. Specifically, the *Lerner* decision notes that the limitation of a "carrier" in claim 4 of the particular application in question did not create a distinction over the art. However, a "carrier" is not analogous to limitations of the pending claims. A "carrier" is inert and frequently serves as nothing more than filler. By contrast, as noted above, an aerosol confers specific advantages as embodied in Claim 22.

Finally, the Examiner cites *In re Riden et al.*, 138 USPQ 112 (1963). Applicants remind the Examiner that a court holding may not be asserted without a determination as to whether the holding is still valid. Applicants point out that the rationale and holding of *In re Riden et al.*, relative to an obviousness rejection based on a primary reference that does not disclose or suggest any usefulness of a claimed composition, has been overruled:

The question remains whether ... Riden state[s] the correct burden of proof to be imposed on an applicant for patent ... We have concluded that [it] does not. ... To the extent that ... Riden [is] inconsistent with the views expressed herein, they no longer will be followed, and are overruled. *In re Stemniski*, 58 CCPA 1410; 444 F2d 581, 170 USPQ 343 (1971).

Applicants argue, as detailed above, that the instant specification provides an ample showing of the advantages and usefulness for a composition comprising an aerosol. As held in *In re Stemniski*, it is not the Applicants' burden to prove a claim's non-obviousness to the Patent Office.

Thus, none of the four cases cited by the Examiner are applicable - let alone dispositive. None of the cases provides a basis or justification for ignoring the claim limitation at issue here.

3. Claims 22-25 and 27-37 Are Not *Prima Facie* Obvious

For a proper rejection, each and every element within the claimed embodiment must be found in the cited art. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. Even if the Examiner does not accept (improperly) that '441 patent is not prior art, the Applicants submit that the Examiner still has not properly established the *prima facie* obviousness of the rejected claims.

Further, the Examiner makes unsupported and conclusory statements, such as:

Therefore it would have been obvious to a person having ordinary skill in the art to include an antibiotic in a solution comprising a sterile liquid and a leukotriene ..., wherein the leukotrienes is LTB4 ..., or wherein the leukotrienes is a cysteinyl leukotriene ... such as leukotrienes C4, D4 and E4 ... because Gosselin et al. suggests to use LTB4 with an antibacterial or antifungal agent against Gram+ and - infections, or fungal infections. *Third Final Office Action* 03/24/04 pg. 3.

The Applicants disagree with the present rejection because the Examiner's statements are: i) unsupported and improper; ii) bald conclusions without a factual basis; and iii) '441 patent does not teach all the claim limitations. Specifically, the Examiner admits that '441 patent does not teach a leukotriene/antibiotic combination:

Gosselin et al. do not expressly teach that to include an antibiotic to the [] solution comprising a sterile liquid and a leukotriene.

Third Final Office Action, 03/24/04 pg 3.

a. Claim 22

In addition to the fact that '441 patent does not teach the claimed leukotriene/antibiotic combination, "an aerosol" or "a sterile liquid" is not taught before the Applicants' priority date. Specifically, these elements are new matter within the '441 patent because the '059 application does not teach these elements.

b. Claim 28

In addition to the fact that '441 patent does not teach the claimed leukotriene/antibiotic combination, '441 patent also does not teach "an intratracheal instillation device" (i.e., for example, a bronchoscope). Additionally, "a sterile liquid vehicle" is not taught before the

Applicant's priority date. Specifically, this element is new matter within the '441 patent because the '059 application does not teach this element.

c. Claim 33

In addition to the fact that '441 patent does not teach the claimed leukotriene/antibiotic combination, '441 patent does not teach "a nebulizer". Additionally, "a sterile liquid" is not taught before the Applicant's priority date. Specifically, this element is new matter within the '441 patent because the '059 application does not teach this element.

d. Conclusion

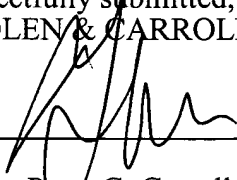
In conclusion, neither the '441 patent nor the '059 application meet the legal standards to support a *prima facie* case of obviousness. Applicants, therefore, respectfully request the Examiner to withdraw the rejection.

Appellants submit that, with due consideration to all these factors discussed above, the patentability of Claims 22-25 and 27-37 is evident. First, the only reference cited by the Examiner ('441 patent) is not prior art for several claim elements (*i.e.*, for example, "a sterile solution" and "an aerosol"). Second, the Examiner has improperly ignored claim elements that confer patentability. Third, even if the standards regarding a *prima facie* case of obviousness are applied against the '441 patent, the rejection fails.

For the foregoing reasons, it is submitted that the examiner's rejections of Claims 22-25 and 27-37 were erroneous, and reversal of these rejections is respectfully requested.

Dated: Jan 17, 2006

Respectfully submitted,
MEDLEN & CARROLL, LLP

By: 
Peter G. Carroll
Reg. No.: 32,837

Attorney for Appellant



III. CLAIMS APPENDIX

22. A solution for the treatment of a microbial infection, said solution comprising a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is an aerosol.
23. The solution of Claim 22, wherein said leukotriene is leukotriene B₄.
24. The solution of Claim 22, wherein said leukotriene is a cysteinyl leukotriene.
25. The solution of Claim 24, wherein said cysteinyl leukotriene is selected from the group consisting of leukotriene C₄, leukotriene D₄, and leukotriene E₄.
27. The solution of Claim 22, wherein said microbial infection comprises *Klebsiella pneumoniae* infection.
28. A solution for the treatment of a microbial infection, said solution comprising a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is in an intratracheal instillation device, said instillation device is selected from the group consisting of an endotracheal tube and a bronchoscope.
29. The solution of Claim 28, wherein said leukotriene is leukotriene B₄.
30. The solution of Claim 28, wherein said leukotriene is a cysteinyl leukotriene.
31. The solution of Claim 28, wherein said cysteinyl leukotriene is selected from the group consisting of leukotriene C₄, leukotriene D₄, and leukotriene E₄.

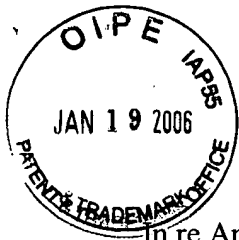
32. The solution of Claim 28, wherein said microbial infection comprises *Klebsiella pneumoniae* infection.
33. A composition for the treatment of a microbial infection comprising, a sterile liquid vehicle, an antibiotic and a leukotriene dissolved in said sterile liquid vehicle, wherein said solution is contained within a nebulizer.
34. The composition of Claim 33, wherein said leukotriene is leukotriene B₄.
35. The composition of Claim 33, wherein said leukotriene is cysteinyl leukotriene.
36. The composition of Claim 33, wherein said cysteinyl leukotriene is selected from the group consisting of leukotriene C₄, leukotriene D₄ and leukotriene E₄.
37. The composition of Claim 33, wherein said microbial infection comprises *Klebsiella pneumoniae* infection.

IX. EVIDENCE APPENDIX

(There are no attachments in this appeal)

X. RELATED PROCEEDINGS APPENDIX

(There are no attachments in this appeal)



AF/1653
PATENT *RFW*

Attorney Docket No. UM-03662

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Marc Peters-Golden *et al.*
Serial No.: 09/291,656
Filed: 03/03/99
Entitled: **ADMINISTRATION OF PRODUCTS OF THE 5-LIPOXYGENASE
METABOLIC PATHWAY TO ENHANCE ANTIMICROBIAL
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Group No.: 1653
Examiner: K. Carlson

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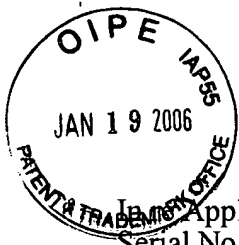
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Applicant's believe *no* fee is required, but if the examiner believes otherwise the Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. **08-1290**. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: January 17, 2006

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